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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,440	09/19/2003	Timothy John Henkel	9404.0005-02	8311

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EXAMINER	
YOUNG, MICAH PAUL	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
07/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/666,440	HENKEL, TIMOTHY JOHN	
	Examiner	Art Unit	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice: Upon Consideration of Arguments Presented in the Appeal Brief dated 3/15/07, prosecution has been re-opened.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

1. Claims 1,4-8,11-26,34 and 35 are rejected under 35 U.S.C. 102(a) as being anticipated by File et al (*Gemifloxacin versus amoxicillin/clavulanate in the treatment of acute exacerbation of chronic bronchitis. The 070 Clinical Study group.* J. Chemotherapy; August 2000; 12(4): 314-25). The claims are drawn to a method of reducing the recurrence of acute exacerbation of chronic bronchitis (AECB) in a patient in need thereof with an effective dosage of gemifloxacin.

2. The reference discloses a study where gemifloxacin is compared to amoxicillin/clavulanate in its treatment of AECB (abstract). The patients participating in the study have been suffering from chronic bronchitis for more two (2) consecutive years, and most days in a period of three (3) months (pg. 315). Gemifloxacin is given orally at 320 mg once daily for five (5) days (pg. 316). Patients were assessed at a follow-up where symptoms and bacterial activity were monitored and recorded (pg 316). The results of the study show that gemifloxacin is just as effective a treatment regimen for AECD as amoxicillin/clavulanate (pg. 323). These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 2,3,9,10,27-33, and 36-42 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of File et al (*Gemifloxacin versus amoxicillin/clavulanate in the treatment of acute exacerbation of chronic bronchitis. The 070 Clinical Study group.* J. Chemotherapy; August 2000; 12(4): 314-25) and Kim et al (WO 98/42705). The claims are drawn to a method of reducing the occurrences of AECB by administering gemifloxacin salts.

6. As discussed above the File study discloses a treatment for the reduction of AECB occurrences by administering gemifloxacin. However the study is silent to eh particular salts of the drug available for use. Kim however discloses these compounds and suggests their use in the treatment of respiratory infections (abstract). The reference discloses various derivatives and salts including mesylate and sesquihydrate salts (pg 10, lin. 6- pg 11 lin 3). It is well within the

level of skill in the art to substitute salts of known compounds into varying treatment regimens, in order to account for difference is solubility or other treatment variables. These substitutions would be obvious to one of ordinary skill in the art.

7. Regarding claims drawn to the specific follow-up regimen it is the position of the Examiner that such limitations do not impart patentability on the claims. The File study teaches that a long-term follow-up procedure is best for monitoring patients, however the specific intervals would be well within the level of skill in the art. Barring a showing of unexpected results regarding the particular follow-up procedures, it is the position of the Examiner that these limitations do not impart patentability.

8. With these things in mind, one of ordinary kill in the art would have been motivated to substitute the salts of Kim into the treatment regimen taught by File in order to account for changes in solubility during the treatment regimen. The artisan of ordinary skill would have been able to make these substitutions with an expected result of a method of reducing AECB occurrences in patients in need thereof.

Response to Arguments

9. Applicant's arguments filed 3/15/07 have been fully considered but they are not persuasive. Applicant argues that:

a. File is not available as prior art since it was not available to the public before the filing date of the priority document.

10. It remains the position of the Examiner that the File reference would have been available to a member of the public before the filing of the priority documents of the instant invention.

According to the publishers of the File article the reference was emailed to subscribers on or around September 1, 2000, approximately two weeks before the filing date of the provisional application. Applicant argues that this date is not official since email receipt cannot be verified. However the article would also have been available to public search engines such as PubMED/ MEDLINE at or around September 1, 2000. As stated in MPEP 2128; A reference is proven to be a "printed publication" "upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it." In re Wyer, 655 F.2d 221, 210 USPQ 790 (CCPA 1981) (quoting I.C.E. Corp. v. Armco Steel Corp., 250 F. Supp. 738, 743, 148 USPQ 537, 540 (SDNY 1966)). In accordance with this citation, an email from the publisher of the article to subscribers (those of ordinary skill in the art with interest in the subject matter would constitute dissemination of the article making the File reference available as prior art.

11. Although prior art reference without dates cannot be relied upon, verification from the publisher can be relied upon as an accurate date check in accordance with the MPEP.

12. For these reasons the claims remain rejected.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young
Examiner
Art Unit 1618

MP Young

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER